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SEP 27 2006

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Serial No.: 10/645,304

Attorney Docket No.: NANO104.00US2

REMARKS

To expedite prosecution and place the instant application in condition for allowance, Applicants have amended independent claims 1, 9, and 17 to more clearly set forth the inventive concept. Specifically, claims 1, 9, and 17 as amended herewith provide for a claim-designated peptide amphiphile compound that self-assembles to form a non-spherical micelle. Support for this limitation is found in the specification as originally filed, *inter alia*, at paragraph 42. Claim 21 was amended to correct a typographical error.

Upon the entry of the instant amendment, claims 1-21 are pending in the application and claims 22-30 are withdrawn. Applicants respectfully request that the Examiner reconsider the outstanding rejections in light of the aforementioned amendments and the following remarks:

Rejections under 35 U.S.C. § 103

Claims 1-8 and 17-21 are rejected under 35 USC 103 as allegedly being unpatentable over Forns et al. in view of Fields et al. and in view of Torchilin, as evidenced by Amino Acid Structures at Physiological pH.

The Examiner states that Forns describes a peptide amphiphile composition comprising a hydrophobic component having a single alkyl group and a hydrophilic component inherently having a net charge at physiological pH. According to the Examiner, Forns describes that such monoalkyl peptide amphiphiles tend to self-assemble as micelles. Forns, according to the Examiner, does not teach using a monoalkyl peptide amphiphile with a negative net charge at physiological pH or the addition of an agent for inducing micelle formation. To remedy this deficiency, the Examiner states that Fields describes a negatively charged monoalkyl peptide amphiphile and Torchilin describes micelle formation induced by agents such as removal of solvent and electrolytes. The Examiner states that it would have been obvious to create self-assembling micelles using the negatively charged monoalkyl peptide amphiphiles because the alkyl chain enhances stability of the structural element and induces

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aggregates of defined sizes according to Forns. Moreover, according to the Examiner, the working conditions such as net charge, specific amino acid composition, and the use of agents to induce micelle formation is that of judicious selection and routine optimization. The Examiner concludes that claims 1-8 and 17-21 are obvious.

Applicants respectfully disagree with the Examiner's contentions. Forns does not, in fact, report the formation of aggregates, but merely states that peptide amphiphiles may self-assemble into micelles. Forns bases its prediction that the disclosed peptide amphiphiles would self assemble into micelles based on the surfactant number and a formulation to predict the geometry of the final amphiphile aggregate. Actual formation of the micelle was not reported. Specifically, Forns states that "micellization is probable" (p. 543, second column) and that "[f]uture studies in this area will be directed toward the manipulation of peptide-amphiphile aggregate structures (i.e., micelles, liposomes, etc.)" (p. 544, second column). Therefore, Applicants respectfully submit that Forns provides merely the basis to try to obtain peptide amphiphiles that self-assemble into micelles. This "obvious to try" standard has been repeatedly rejected by the courts and is not remedied by the cited secondary references, Fields and Torchilin.

Fields is cited to describe the use of negatively charged peptide amphiphiles and Torchilin is cited to describe the use of micelle-inducing agents. However, neither Fields nor Torchilin describe that the peptide amphiphiles of Forns would self-assemble into micelles. Moreover, in view of the fact that Forns does not report the self-formation of micelles, Applicants respectfully submit that there is no reasonable expectation of success that such aggregates would be formed using negatively charged peptide amphiphiles or the micelle-inducing agents. Forns itself does not teach such success and therefore, no *prima facie* case of obviousness has been made.

Nevertheless, in order to expedite the prosecution of the present application, Applicants have amended the independent claims to recite that the peptide amphiphiles form non-spherical micelles. By its own contention, Forns predicts that the peptide amphiphiles described therein would form spherical micelles. See page 543, second column. By its own admission and based on the peptide described therein, there is no

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reasonable expectation that Forns' peptide amphiphiles would form anything other than spherical micelles.

Reconsideration of the rejection and withdrawal of the rejection is respectfully requested.

Claims 9-16 are rejected under 35 USC 103 as allegedly being unpatentable over Forns et al. in view of Fields et al. as evidenced by Amino Acid Structures at Physiological pH.

According to the Examiner, Forns and Fields do not describe a peptide amphiphile compound comprising an alkyl tail, a structural peptide covalently bonded to the alkyl tail, and a functional peptide covalently bonded to the structural peptide opposite the alkyl tail. Fields is cited to describe that monoalkyl peptide amphiphiles may be used in the formation of bilayer membrane systems. Forns is further cited to describe aggregation in geometric forms such as alpha-helical and triple-helical, but not conical. The Examiner states that it would have been obvious to modify the compositions of Forns and Fields to create a surface-coating peptide amphiphile as described by Fields because such peptide amphiphiles have been shown to promote cellular recognition and signaling.

Applicants respectfully submit that each and every element of the claims 9-16 have not been met by this combination of references. Nevertheless, in order to expedite the prosecution of this application, Applicants have amended claim 9 to recite that the claim-designated peptide amphiphile compound self-assembles into a non-spherical micelle. As discussed above, neither Forns nor Fields describes the self-assembly of its peptide amphiphiles into non-spherical micelles. Indeed, neither Forns nor Fields reports the actual formation of micelles at all. As such, Applicants respectfully request reconsideration of the application and withdrawal of the instant rejection.

Double Patenting Rejections

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over one or more claims of the following co-

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pending applications: 11/005,552, and 11/005,314. However, M.P.E.P. 706.02(k) states that where two applications of different inventive entities are co-pending and the filing dates differ, a provisional rejection should be made in the later filed application if the applications have a common assignee or a common inventor. Where the applications are claiming the same patentable invention, a terminal disclaimer may be used to overcome a rejection in a common ownership situation if the earlier filed application has matured into a patent.

In this case, these two co-pending applications cited by the Examiner were filed after the present application. Accordingly, the inclusion of such provisional rejections is improper. Moreover, submission of a terminal disclaimer is only appropriate when the earlier filed application (i.e., the present application) has matured into a patent. Thus, Applicants respectfully submit that the outstanding provisional rejections based on later filed applications should be withdrawn from this, the earlier filed application. Should the provisional double patenting rejections be maintained, Applicants wish to hold in abeyance the filing of a terminal disclaimer until such point as the claims of the instant application are in condition for allowance.

Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over one or more claims of the following co-pending application: 10/368,517. Applicants respectfully request that this rejection be held in abeyance until allowable claims of the instant application are indicated at which time Applicants will consider filing a terminal disclaimer.

Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,890,654. Applicants respectfully request that this rejection be held in abeyance until allowable claims of the instant application are indicated at which time Applicants will consider filing a terminal disclaimer.

Further to the Examiner's request concerning related applications, Applicants provide the attached Exhibit 1 to identify other applications that may describe peptide amphiphiles.

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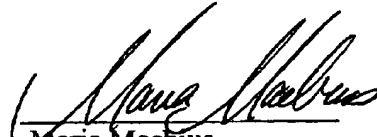
In sum, Applicants respectfully submit that the amendments and remarks herein render moot the outstanding rejections set forth in the Office Action mailed June 27, 2006, and place the instant application in condition for immediate allowance. However, in the event the Examiner believes a conference would expedite prosecution, he is courteously invited to contact the undersigned.

The previous Office Action set forth a three-month period for response, response being due on or before **September 27, 2006**. Accordingly, Applicants submit that this response is timely and no additional fee is required.

Respectfully submitted,

Date: 27 SEPTEMBER 2006

By

  
Maria Macbius  
Attorney for Applicant  
Registration No. 42,967

Benet Group  
c/o Intellevate  
P.O. Box 52050  
Minneapolis MN 55402  
Telephone: 202-253-7199  
Facsimile: 612-677-3572

**CUSTOMER NUMBER 62249**

## Exhibit 1 NANO104 Amendment

Serial#	Title	Matter Type	Status
10/294,114	SELF-ASSEMBLY AND MINERALIZATION OF PEPTIDE-AMPHIPHILE NANOFIBERS	Utility - ORG	Pending
10/367,517	SELF-ASSEMBLY OF PEPTIDE-AMPHIPHILE NANOFIBERS UNDER PHYSIOLOGICAL CONDITIONS	Utility - NPREG	Pending
10/368,517	SELF-ASSEMBLY OF PEPTIDE-AMPHIPHILE NANOFIBERS UNDER PHYSIOLOGICAL CONDITIONS	Utility - NPREG	Pending
10/405,143	PEPTIDE-AMPHIPHILE SOLUTIONS & SELF ASSEMBLED PEPTIDE NANOFIBER NETWORKS	Utility - ORG	Pending
10/645,304	CHARGED PEPTIDE-AMPHIPHILE SOLUTIONS & SELF-ASSEMBLED PEPTIDE NANOFIBER NETWORKS FORMED THEREFROM	Utility - NPREG	Pending
10/645,304	SELF-ASSEMBLED PEPTIDE NANOFIBER NETWORKS PRESENTING MULTIPLE SIGNALS	Utility - ORG	Expired

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## Exhibit 1 NANO104 Amendment

10/668,672	SELF-ASSEMBLED PEPTIDE-AMPHIPHILES & SELF-ASSEMBLED PEPTIDE NANOFIBER NETWORKS PRESENTING MULTIPLE SIGNALS	Utility - ORG	Pending
10/720,689	COMPOSITION AND METHOD FOR SELF- ASSEMBLY AND MINERALIZATION OF PEPTIDE- AMPHIPHILES	Utility - ORG	Pending
10/534,097	COMPOSITION AND METHOD FOR SELF- ASSEMBLY AND MINERALIZATION OF PEPTIDE- AMPHIPHILES	Utility - NSPCT	Pending
10/534,266	SYNTHESIS AND SELF-ASSEMBLY OF ABC TRIBLOCK BOLA PEPTIDE	Utility - NSPCT	Pending
11/005,552	SELF-ASSEMBLING PEPTIDE AMPHIPHILES AND RELATED METHODS FOR GROWTH FACTOR DELIVERY	Utility - NPREG	Pending
10/720,689	COMPOSITION AND METHOD FOR SELF- ASSEMBLY AND MINERALIZATION OF PEPTIDE- AMPHIPHILES	Utility - ORG	Pending

## Exhibit 1 NANO104 Amendment

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11/005,314	BRANCHED PEPTIDE AMPHIPHILES, RELATED EPI TOPE COMPOUNDS AND SELF ASSEMBLED STRUCTURES THEREOF	Utility - NPREG	Pending
60/495,965	METHODS AND MATERIALS FOR THE GROWTH OF NANOCRYSTALLINE COATINGS ON SURFACES	Prov - ORG	Expired
60/645,668	METHODS AND COMPOSITIONS FOR ENCAPSULATION OF CELLS	Prov - ORG	Expired
60/658,503	ANGIOGENIC HEPARIN-BINDING EPITOPES, PEPTIDE AMPHIPHILES, SELF-ASSEMBLED HYDROGELS AND RELATED METHODS	Prov - ORG	Expired



## Exhibit 1 NANO104 Amendment

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60/397,800	SELF-ASSEMBLED HYBRID COMPOSITIONS AND METHOD OF MAKING, USING AND ORDERING SAME	Prov - ORG	Expired
60/425,536	SELF ASSEMBLY OF MULTI-DIMENSIONAL PEPTIDE AMPHIPHILES	Prov - ORG	Expired